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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/691,053	10/19/2000	Zvia Agur	Q60688	5359

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SUGHRUE, MION, ZINN, MACPEAK & SEAS, PLLC
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EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/03/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/691,053

Applicant(s)

AGUR ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-509 is/are pending in the application.
- 4a) Of the above claim(s) 1-233, 248-465 and 480-509 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 234-247 and 466-479 is/are rejected.
- 7) ☒ Claim(s) 241 and 246 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. All rejections and objections not reiterated below are hereby withdrawn.

Election/Restrictions

This application contains claims 1-233, 248-465, and 480-509 drawn to an invention nonelected with traverse in Paper No. 15. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-233, 248-465, and 480-509 are again withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 15.

An action on the merits of elected claims 234-247 and 466-479 follows.

Claim Objections

Claims 241 and 246 are objected to because of the following informalities. In line 2 of claim 241, a comma or semicolon should be inserted after "tumor". In claim 246, the term "pharmockinetics" should be --pharmacokinetics--. Appropriate correction is required.

Declaration under 37 CFR 1.131

The declaration filed on 3/18/03 under 37 CFR 1.131 has been considered but is ineffective to overcome the ILIADIS et al. reference for the following reasons:

The declaration is not signed by all of the inventors of record. If all of the inventors of record did not invent the subject matter of all of the claims, then applicant is required to show

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that less than all named inventors invented the subject matter of the rejected claims. All of the inventors of the subject matter of the rejected claims must sign a declaration or affidavit made under 37 CFR 1.131. See MPEP 715.04 (A) and (B).

Based on the evidence presented in the List of Exhibits filed with the declaration, the invention appears to have been made outside of the US; however, the declaration does not state where the activities of conception and reduction to practice of the instant invention were conducted. The 37 CFR 1.131 declaration must contain an allegation that the acts relied upon to establish the date prior to the reference or activity were carried out in this country or in a NAFTA country or WTO member country. See 35 U.S.C. 104.

The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the ILIADIS et al. reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897).

Applicant points to an "overall concept diagram" presented in a meeting held 8/7/1999 as proof of conception of the claimed invention. The rejected claims are directed to a system and method of use of the system, for recommending an optimal treatment protocol for treating cancer using drugs, wherein the system comprises a cancer system model, a treatment protocol generator for *generating* a plurality of treatment protocols, a system *model modifier*, wherein the model modifier is adapted to modify the cancer model based on parameters specific to an individual, and a selector for selecting from among the plurality of treatment protocols. The claimed method recites *creating* a system cancer model, enumerating a plurality of treatment protocols, modifying the system model based on parameters specific to an individual, selecting

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an optimal protocol, and recommending the optimal protocol. The emphasis has been added by examiner to clarify the following points. Exhibit 1, purporting to contain diagrams showing conception of the claimed invention, contains two diagrams relating to cancer. A third diagram, relating to bone marrow, is not pertinent as the rejected claims are not directed to a bone marrow system or model. The diagrams labeled "OPTIMA project" and "VBM+OPTIMA" project are similar. Both diagrams show a protocol space containing a cancer module and a connected patient's module, wherein both modules appear to receive or otherwise interact with information from patient's parameters. If the cancer module represents a "cancer system model", then the model does appear to be connected in some fashion to a patient's parameters. Whether the "model" is actually modified (i.e. changed) by the patient's parameters is not clear. The module may simply incorporate the patient's parameters at t_0 for later use or comparison to data collected later, but there is no indication in either diagram that the module (model?) is actually *modified* by the parameters. Mere addition of data does not constitute modification of a model *per se*. In addition, the diagrams do not indicate anywhere whether the module represents a model which has been *created* or one which was previously known. The diagrams do not show or otherwise indicate any module or step corresponding to a "treatment protocol generator for generating a plurality of treatment protocols..." or for "enumerating a plurality of treatment protocols". It is noted that some variety of treatment conditions may be part of a previously known cancer model, and would not require specific "enumeration." There is no module or step for generating or enumerating anything in either diagram, specifically for "*generating [enumerating]* a plurality of treatment protocols..." There is a search module which connects to an "optimal protocol", therefore, although the diagrams do not specifically show a "selector", a "selecting" step is implied and a selector must exist to provide or "select" an optimal protocol. In conclusion, while the diagrams indicate that a cancer model may have been

part of the conception, there is no indication that the model was intended to be modified by patient's parameters, therefore the diagram does not indicate conception of a "system model modifier...adapted to modify said cancer system model based on parameters specific to the individual." There is nothing in either diagram that shows conception of "a treatment protocol generator" or "enumeration" of a plurality of treatment protocols as part of the system or method. A selector/selection step for selecting an optimal treatment is merely implied, but does appear to be part of the system and method conceived of; however, a selector to select from a plurality of *generated or enumerated protocols* based on a *modified* cancer model does not appear to have been part of the invention conceived of as represented by the diagrams.

Appendix C, shown as Exhibit 14, discusses a system/method which appears to be close to that of the claimed invention. While Appendix C is not dated, an Appendix C is referred to in Exhibit 7, which contains a date of July 31, 2000. The earliest date that can be attributed to Appendix C, therefore, is 7/31/2000. It is noted that this is AFTER the publication date of ILIADIS et al. Appendix C is noted here because it appears to be the closest evidence for "conception" of the claimed invention. The General Description part of this Exhibit discloses developing cancer models, inputting individual parameters into the model, and using search algorithms to search through possible protocols to obtain a best/most suitable solution. A "general fitness function" is also described, but this does not appear to correspond to a "treatment protocol generator" or a step of generating treatment protocols. The Fitness Function is defined on a later page of the Exhibit 14 as a tool for comparison of different treatment protocols, therefore the "fitness function" appears to correspond to the "selector" of the rejected claims. Thus, even as late as 7/31/2000, an invention comprising all of the CLAIMED parts/steps (specifically, one comprising a generator of treatment protocols) did not appear to have been conceived of.

The examiner has reviewed all of the exhibits filed with the declaration of 3/18/03, but found no evidence that the entirety of the claimed invention was conceived of prior to the actual filing date of the instant application, of October 19, 2000.

Claim Rejections - 35 USC § 112

Claims 234-247 and 466-479 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has amended the claims, but has not set forth any arguments with regard to how or why the amendments overcome the rejections and/or render the claims definite.

Amended claims 244 and 476 recite "pharmacokinetics, pharmacodynamics, ..." The specification discloses the terms "pharmacokinetic" and "pharmacodynamic" throughout, and specifically with regard to optimal treatment protocols on page 5. The specification does not disclose if the terms are intended to be methods, models, interactions, reactions, etc. The specification does not disclose or define the terms "pharmacokinetics" or "pharmacodynamics" anywhere. As the plural terms are interpreted by the examiner to be equivalent to the singular, use of the plural is not considered to be new matter. However, applicant is advised that if the plural is intended to be different from the singular, or is defined differently, then the plural terms may be new matter, and the claims will be rejected. As the limitation intended by applicant for the terms is still unclear, the examiner maintains that the claims are indefinite, and the rejection is maintained.

Amended claims 246 and 478 similarly recite "patient specific drug pharmacokinetics, pharmacodynamics ..." but does not recite if these are interactions, reactions, parameters, models, etc. See above with regard to the singular/plural forms of the terms "pharmacokinetic"

and "pharmacodynamic." As the limitations intended by use of these terms is still unclear, the examiner maintains that the claims are indefinite, and maintains the rejection.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. Applicant is reminded that, as previously set forth in the Office Action of 11/18/02: "In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a)."

Claims 234-235, 246-247, 466-467, and 478-479 are again rejected, as set forth in the Office Action of 11/18/02, under 35 U.S.C. 103(a) as being unpatentable over ILIADIS et al. (IDS ref: Computers and Biomed. Res. (2000), vol. 33, pages 211-226).

Claims 234-242, 244-247, 466-474, and 476-479 are rejected, as set forth in the Office Action of 11/18/02, under 35 U.S.C. 103(a) as being unpatentable over ILIADIS et al. (IDS ref: Computers and Biomed. Res. (2000), vol. 33, pages 211-226) in view of PERIERA et al. (IDS ref: Frontiers Med. Biol. Eng. (1995), vol. 6 (4), pages 257-268).

Claims 243 and 475 are rejected, as set forth in the Office Action of 11/18/02, under 35 U.S.C. 103(a) as being unpatentable over ILIADIS et al. (IDS ref: Computers and Biomed. Res. (2000), vol. 33, pages 211-226) in view of PERIERA et al. (IDS ref: Frontiers Med. Biol. Eng. (1995), vol. 6 (4), pages 257-268) as applied to claims 234-242, 244-247, 466-474, and 476-479, above, and further in view of LEMELSON (US 5,919,135).

Applicant's arguments and the AGUR declaration have been fully considered but are not persuasive. Applicant argues that as the AGUR declaration shows conception of the claimed invention prior to the publication date of ILIADIS et al., ILIADIS et al. does not qualify as prior art, therefore all of the rejections set forth above have been overcome. In response, applicant is directed to the reasons set forth above which set forth why the AGUR declaration (a) is not a proper declaration under 37 CFR 1.131 and (b) does not show conception of the CLAIMED invention prior to the publication date of ILIADIS et al. As the AGUR declaration does not disqualify ILIADIS as prior art, and applicant has not amended the claims to overcome the rejections under 35 USC 103, the examiner maintains that ILIADIS, ILIADIS in view of PERIERA, and ILIADIS in view of PERIERA and LEMELSON make obvious all of the elected claims, and maintains all of the rejections.

Conclusion

Claims 234-247 and 466-479 are again rejected; claims 1-233, 248-465, and 480-509 are again withdrawn.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

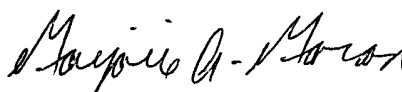
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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.


MARJORIE MORAN
PATENT EXAMINER

mam
May 31, 2003